

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)



(PCT Article 36 and Rule 70)

REC'D 13 JUN 2006

WFO PCT

Applicant's or agent's file reference PCTA9407-2	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/KR2004/001819	International filing date(day/month/year) 21 JULY 2004 (21.07.2004)	Priority date (day/month/year) 30 JANUARY 2004 (30.01.2004)	
International Patent Classification (IPC) or national classification and IPC C12N 15/54(2006.01)i, C12N 15/04(2006.01)i, C12N 9/10(2006.01)i			
Applicant Korea Research Institute of Bioscience and Biotechnology et al			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: <ul style="list-style-type: none"> a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand 26 OCTOBER 2005 (26.10.2005)	Date of completion of this report 18 MAY 2006 (18.05.2006)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer KIN, Ji Yun Telephone No. 82-42-481-8288 

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☒ This report is based on translations from the original language into the following language English which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☒ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☒ the international application as originally filed/furnished

 - ☐ the description:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☐ the claims:
 - pages _____ as originally filed/furnished
 - pages* _____ as amended (together with any statement) under Article 19
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☐ the drawings:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☒ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 11

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 11

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-10	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims	None	NO

2. Citations and explanations (Rule 70.7)

(1) The following documents have been considered for the purpose of this report;

D1: Proc. Nat'l. Acad. Sci. Vol. 100, pp. 5022-5027 (April 2003)

D2: Glyobiology, Vol. 5, pp. 671-681 (1995)

D3: J. Biol. Chem., Vol. 273, pp. 26298-26304 (October 1998)

D4: J. Biol. Chem. Vol. 268, pp. 26338-26345 (December 1993)

D5: US 2004/0137134 A (26 September 2002)

D6: KR 2004/0004089 (13 January 2004)

(2) Novelty and Inventive Step

The present invention relates to a novel α -1,6-mannosyltransferase gene from *Hansenula polymorpha* which codes for enzyme initiating outer chain elongation in N-linked glycosylation. It also discloses a process for producing a glycoprotein without human incompatible sugar chain using α -1,6-mannosyltransferase deficient mutant of *H. polymorpha*.

Claims 1-7 relate to a nucleic acid encoding a protein of an amino acid according to SEQ ID No. 2 or a protein with α -1,6-mannosyltransferase activity having an amino acid at least 90% homologous to SEQ ID No. 2, a protein coded by said nucleic acid, a recombinant vector comprising a nucleic acid according to SEQ ID No. 1(KCTC 10583BP), and a *H. polymorpha* mutant strain having a deficiency in the α -1,6-mannosyltransferase gene(KCTC 10584BP). Claims 8-10 relate to a process for producing a glycoprotein with reduced glycosylation using said mutant yeast.

(Continued on Supplemental Sheet.)

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

a. type of material

☒

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☒

on paper

☒

in electronic form

c. time of filing/furnishing

☒

contained in the international application as filed

☒

filed together with the international application in electronic form

☐

furnished subsequently to this Authority for the purposes of search and/or examination

☐

received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed of furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box No. V

D1 to D5 disclose α -1,6-mannosyltransferases from various yeast strains. In addition, the documents also disclose that α -1,6-mannosyltransferase can be used for producing glycoengineered protein, especially characterized by having a structure of Man5GlcNAc2 and Man8GlcNAc2.

D5 and D6 disclose a method for producing glycoproteins having a similar glycosylation pattern to the one produced in human by introducing a gene encoding enzyme involved in glycosylation including α -1,6-mannosyltransferase.

However, the documents set forth above do not provide any amino acid or nucleotide sequence with significant homology to the sequences provided in this invention, or fairly suggest a mutant deficient in α -1,6-mannosyltransferase gene and a method of production of glycoprotein using said mutant.

Thus, claims 1-10 are novel and involve an inventive step [PCT Article 33(2) and 33(3)].

(3) Industrial Applicability

The subject matter of claims 1-10 is considered to be industrially applicable under PCT Article 33(4).